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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,830	01/30/2002	Yizhong Gu	PB0169	3442

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EXAMINER
SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,830		
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 32, 33, and 39, drawn to isolated nucleic acids, classified in class 536, subclass 23.2.

II. Claims 13-18, 34, 35, and 40, drawn to polypeptides, classified in class 435, subclass 212.

III. Claims 19, 28, 36, 37, 38, and 41, drawn to binding partners, classified in class 530, subclass 389.1.

IV. Claim 20, drawn to a transgenic non-human animal containing nucleic acid molecules, classified in class 800, subclass 8.

V. Claim 21, drawn to a transgenic non-human animal unable to express endogenous nucleic acid molecules, classified in class 800, subclass 8.

VI. Claim 22, drawn to a method for identifying modulators of LCP expression, classified in class 435, subclass 6.

VII. Claim 23, drawn to a method for identifying agonist and antagonist of LCP, classified in class 435, subclass 23.

VIII. Claims 24 and 42, drawn to an agonist to the polypeptide, classified in class 514, subclass 789.

IX. Claims 25 and 43, drawn to an antagonist to the polypeptide, classified in class 514, subclass 789.

X. Claim 26, in part, drawn to a method for identifying binding partners in vitro, classified in class 435, subclass 23.

XI. Claims 26, in part, and 27, drawn to a method for identifying binding partners in vivo, classified in class 435, subclass 23.

XII. Claim 29, drawn to a method for detecting a target nucleic acid, classified in class 435, subclass 6.

XIII. Claim 30, drawn to a method for diagnosing a disease caused by a mutation in LCP, classified in class 435, subclass 6.

XIV. Claim 31, drawn to a method for diagnosing or monitoring a disease caused by altered expression of LCP, classified in class 435, subclass 6.

XV. Claim 44, in part, drawn to a method for preventing or treating a disorder associated with decreased expression or activity of LCP comprising administering a nucleic acid, classified in class 514, subclass 44.

XVI. Claim 44, in part, drawn to a method for preventing or treating a disorder associated with decreased expression or activity of LCP comprising administering a polypeptide, classified in class 514, subclass 2.

XVII. Claim 44, in part, drawn to a method for preventing or treating a disorder associated with decreased expression or activity of LCP comprising administering an agonist, classified in class 514, subclass 789.

XVIII. Claim 45, in part, drawn to a method for preventing or treating a disorder associated with increased expression or activity of LCP comprising administering an antibody, classified in class 424, subclass 139.1.

XIX. Claim 45, in part, drawn to a method for preventing or treating a disorder associated with increased expression or activity of LCP comprising administering an antagonist, classified in class 514, subclass 789.

XX. Claim 46, drawn to a method for modulating the expression of a nucleic acid, classified in class 514, subclass 44.

XXI. Claim 47, drawn to a method for modulating the activity of a polypeptide, classified in class 435, subclass 212.

The above inventions are distinct because of the following reasons.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Invention I is unrelated to Inventions III, VIII, and IX because the products of Invention I are physically and functionally distinct chemical entities from the products of Inventions III, VIII, and IX.

Invention II is unrelated to Inventions IV and V because the products of Invention II are physically and functionally distinct chemical entities from the products of Inventions IV and V.

Inventions III, IV, V, VIII, and IX are unrelated because the products of each of these inventions are physically and functionally distinct chemical entities.

The methods of Inventions VI, VII, and X-XXI are distinct because they have different modes of operation, different functions, and/or different effects.

The products of Invention I are unrelated to the methods of Inventions VII, X, XI, XVI, XVII, XVIII, XIX, XX, and XXI because said methods can neither use the products of Invention I nor be used to make said products.

The products of Invention II are unrelated to the methods of Inventions VI, XII, XIII, XIV, XV, XVII, XVIII, XIX, XX, and XXI because said methods can neither use the products of Invention I nor be used to make said products.

The products of Invention III are unrelated to the methods of Inventions V, VI, VII, XI, XII, XIII, XV, XVI, XVII, XIX, and XX because said methods can neither use the products of Invention I nor be used to make said products.

The products of Invention IV are unrelated to the methods of Inventions VI, VII, X, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, and XXI because said methods can neither use the products of Invention I nor be used to make said products.

The products of Invention V are unrelated to the methods of Inventions VI, VII, X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, and XXI because said methods can neither use the products of Invention I nor be used to make said products.

The products of Invention VIII are unrelated to the methods of Inventions VI, XII, XIII, XIV, XV, XVI, XVIII, XIX, and XX because said methods can neither use the products of Invention I nor be used to make said products.

The products of Invention IX are unrelated to the methods of Inventions VI, XII, XIII, XIV, XV, XVI, XVII, XVIII, and XX because said methods can neither use the products of Invention I nor be used to make said products

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since, the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acids of Invention I are related to the transgenic animals of Inventions IV and V by virtue of being the nucleic acid used to make said animals. Although the nucleic acid molecules and the animals are related, they are distinct inventions because they are physically and functionally distinct chemical entities, and the DNA may be used for processes other than the production of the transgenic animals, such as nucleic acid hybridization assay.

The proteins of Invention II are related to the antibodies of Invention III by virtue of being the cognate antigen necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists or antagonists of the enzyme.

The proteins of Invention II are related to the agonists and antagonists of Inventions VIII and IX by virtue of being the enzyme that binds and is regulated by said angonists and

antagonists. Although the proteins are related to the agonists and antagonists due to the necessary steric complementarity, they are distinct inventions because they are physically and functionally distinct chemical entities and because the enzyme can be used in another and materially different process from the identification of agonists or antagonists, such as in a pharmaceutical composition in its own right or production of antibodies.

The methods of Invention XX are related to the transgenic animals of Inventions IV and V as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). In the instant case the process can be used to make any transgenic animal as well as treatment for a disease wherein the level of nucleic acids are altered, as described for Invention XV.

When Inventions are related as products and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

The methods of Inventions VI, XII, XIII, XIV, can XV can use the DNA of Invention I; however, said DNA can also be used to make the encoded protein.

The methods of Invention VII, X, XI, and XVI can use the protein of Invention II; however, said protein can also be used for production of antibodies.

The methods of Inventions X, XIV, XVIII, and XXI can use the antibodies of Invention III; however, said antibodies can also be used for immunocytochemistry.

The methods of Invention VII, X, XI, XVII, and XXI can use the agonist of Invention VIII; however, said agonist can also be used for purifying the enzyme.

The methods of Invention VII, X, XI, XIX, and XXI can use the antagonist of Invention IX; however, said antagonist can also be used for purifying the enzyme.

The method of Invention XI can use the transgenic animals of Invention IV; however, said animals can also be used as models for diseases involving increased expression of the DNA.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 8:30-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan L. Swope, Ph.D.

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600